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QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE, SUITE 2040
MILWAUKEE, WI 53202-4497

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ARNOLD, ERNST V	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/756,719
Filing Date: January 13, 2004
Appellant(s): COOK ET AL.

Zhibin Ren
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/5/08 appealing from the Office action mailed 8/14/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,395,782	Cooke et al.	5-2002
6,245,811	Horrobin et al.	6-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3 and 5-16 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 6,395,782) in view of Horrobin et al. (US 6,245,811).

Applicant claims a method of treating rheumatoid arthritis by administering conjugated linoleic acid.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Cook et al. teach methods of extending the survival time of a human or non-human animal having a disease, thus in need of treatment, characterized by autoimmune complexes by administering an effective amount of conjugated linoleic acid (Claim 1). Cook et al. teach

isomers of conjugated linoleic acid (column 4, lines 40-45). Cook et al. teach methods suitable for treating rheumatoid arthritis (column 3, lines 37-60). Cook et al. teach feeding, thus oral administration, mice diets of conjugated linoleic acid and corn oil (column 4, lines 49-54). It is the Examiner's position that corn oil can serve as a carrier. Cook et al. teach conjugated linoleic acid in the range of about 0.05% to about 2.0% in the diet or about 0.1 to 10g/day (column 4, lines 15-20).

Horrobin et al. teach and suggest a method for treating a disorder (rheumatoid arthritis) comprising administering to a patient in need thereof an effective amount of the compound according to claim 1 where R_1 is an acyl moiety corresponding to an acid (conjugated linoleic acid) (Column 14 lines 55-62; column 15, line 1 and claims 1, 10 and 28). The Examiner interprets the compound to be an ester of conjugated linoleic acid. Doses may be administered to the patient in need thereof orally, enterally, topically, parenterally, (subcutaneously, intramuscularly, intravenously), rectally, vaginally or by any other appropriate route (Column 17, lines 32-36 and claim 28). By patient, the Examiner interprets this to be a human. Horrobin et al. teach that the compound can be in a food or nutritional supplement (Claim 40).

Horrobin et al. disclose in claim 28 a method of treating a disorder selected from the group consisting of…rheumatoid arthritis…comprising administering to a patient in need thereof an effective amount of the compound of claim 10. Horrobin et al. disclose in claim 10 a compound according to claim 1 where R1 is an acyl moiety corresponding to…conjugated linoleic acid. Therefore, it is the Examiner's position that Horrobin et al. teach or suggest a method of treating rheumatoid arthritis with a compound containing conjugated linoleic acid.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Cook et al. do not expressly teach a method wherein the conjugated linoleic acid is an ester of a conjugated linoleic acid.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use an ester of conjugated linoleic acid, as suggested by Horrobin et al., in the method of treating rheumatoid arthritis as taught by Cook et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Horrobin et al. suggests that esters of conjugated linoleic acid can be used in a method of treating rheumatoid arthritis. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (In re Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); In re Bode 193 USPQ 12 (CCPA) 1976).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

(10) Response to Argument

Appellant agrees with the Examiner that Cook et al. teach administering conjugated linoleic acid to a human or non-human animal that suffers from, for example, rheumatoid arthritis (page 5 of Appeal Brief). Appellent asserts that Cook et al. did not teach that CLA can reduce joint redness and swelling of rheumatoid arthritis. It is the Examiner's position that treatment of a condition does reduce the symptoms of the condition otherwise it would not be a treatment of the condition. Thus, administering conjugated linoleic acid to the patient would intrinsically reduce the symptoms of rheumatoid arthritis including joint inflammation resulting in improvement of joint redness and swelling. The Examiner cannot be anymore clear on the subject. All further arguments related to joint redness and swelling are not found to be persuasive.

Appellant continues their arguments on page 6 of the Appeal Brief by stating: "The use of conjugated linoleic acid to reduce joint redness and swelling in a rheumatoid arthritis patient is not obvious over Cook et al. (a) Cook et al. do not teach that conjugated linoleic acid can

reduce joint redness and swelling. Cook et al. teach that administering conjugated linoleic acid to a human or non-human animal having a condition associated with the existence of autoimmune complexes can extend the survival time and reduce body weight wasting of the human or non\-human animal (see e.g., column 2, line 63 to column 3, line 30). Cook et al. teach that such conditions include rheumatoid arthritis". As admitted by Appellant, conjugated linoleic acid is used to treat rheumatoid arthritis. Treatment of the pathology includes the symptoms of the pathology such as joint redness and swelling. The Examiner cannot be anymore clear on the subject.

On page 7 of the Appeal Brief, Appellant now admits that it is irrelevant whether conjugated linoleic acid intrinsically reduces joint redness and swelling. Appellant continues this line of argument that it is not obvious that conjugated linoleic acid can reduce joint redness and swelling based on the teachings of Cook et al. The Examiner cannot agree for the reasons set forth above. Appellant continues to argue on page 10 of the Appeal Brief that "one of ordinary skill in the art is more likely to conclude that conjugated linoleic acid extends the life span and reduces body weight wasting in rheumatoid arthritis by other mechanisms such as improving feed behavior (US patent 5,428,072) rather than reducing the formation and deposit of antibody/antigen immune complexes, which underlies joint redness and swelling." **This is an incorrect interpretation of the art.** Cooke et al. clearly teach in claim 1 that the animal treated has a disease characterized by autoimmune complexes. *Cooke et al. teach that conjugated linoleic acid exerts its action by reducing the ability of macrophages to associate with autoantibodies to form the damaging immune complexes (Cooke et al. column 3, lines 12-30). A proper conclusion is that one of ordinary skill in the art would expect the conjugated linoleic*

acid to reduce the formation of immune complexes and therefore decrease joint redness and swelling found in rheumatoid arthritis.

Appellant asserts that Horrobin et al. do not teach that an ester of conjugated linoleic acid can be used to treat rheumatoid arthritis. The Examiner strongly disagrees with this assertion. The reference of Horrobin et al. is relied upon for the teaching of treatment of rheumatoid arthritis with esters of conjugated linoleic acid which is clearly disclosed in claim 28. Appellant's further arguments are moot because the art, Cooke et al., does teach administration of conjugated linoleic acid to reduce immune complex formation for the treatment of rheumatoid arthritis as explained above. Therefore, the instant claims remain obvious and one of ordinary skill in the art would have more than a reasonable expectation of success in reducing redness and swelling by administration of conjugated linoleic acid to a patient suffering from rheumatoid arthritis.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616

/Ernst V Arnold/

Examiner, Art Unit 1616

/Robert A. Wax/

Robert A. Wax
TQAS Appeals Specialist
Technology Center 1600